78-605

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1978

UNITED STATES OF AMERICA, ET. AL,. PETITIONERS

v.

GLENN L. RUTHERFORD, ET.AL.

# AMICUS CURIAE BRIEF BY THE NORTHWEST ACADEMY OF PREVENTIVE MEDICINE IN SUPPORT OF GLENN L. RUTHERFORD, ET AL.

## MOTION FOR LEAVE OF LATE FILING OF AMICUS CURIAE BRIEF

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IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1978

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| UNITED STATES OF AMERICA, ET AL., Petitioner, v. GLENN L. RUTHERFORD, Respondent. | NO. 78-605 MOTION FOR LEAVE OF LATE FILING OF AMICUS CURIAE BRIEF |

COMES NOW GEORGE WM. CODY, counsel for the NORTHWEST ACADEMY OF PREVENTIVE MEDICINE, with regard to their interests Amicus Curiae, and moves this Court for Leave of Late Filing of Amicus Curiae Brief, filing date being on or before the 6th day of April, 1979.

This Motion is based upon the records and files herein and upon the following affidavit of GEORGE WM. CODY.

CODY, HATCH, & BEDLE, INC.,P.S.

/s/

GEORGE WM. CODY, General Counsel
DANIEL SMITH, Counsel and Member of the Supreme Court Bar

STATE OF WASHINGTON)
COUNTY OF SNOHOMISH) ss

GEORGE WM. CODY; being first duly sworn upon oath deposes and says:

I am one of the counsel for the Northwest Academy of Preventive Medicine.

The interests of the Northwest Academy are such that their Amicus Curiae brief will present a viewpoint of value to the Court in determining this case. This case is very important to the interests of many physicians and their patients and is of first impression in this Court.

The Government's Brief with regard to the case, UNITED STATES OF AMERICA, ET.AL., v. RUTHERFORD, did not arrive in our office until the 26th day of March, 1979. The preparation of the Government's Brief was relief upon for the preparation of the Amicus Curiae Brief with respect to the Northwest Academy of Preventive Medician. That two weeks time for preparation and printing of a brief is insufficient to prepare a proper document

for filing, and delivery to a printer for required printing.

/s/
GEORGE WM. CODY

SUBSCRIBED AND SWORN TO before me this____ day of_____, 1979.

Notary Public in and for the State of Washington residing at_____

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## INTERESTS OF THE PARTY AMICUS CURIAE

The Northwest Academy of Preventive Medicine is an association of doctors from various healing arts, including physicians and surgeons, osteopaths and surgeons, dentists, chiropractors, naturopathic physicians and members of other associated healing arts.

The purpose of the Academy is to further preventive medicine by: (1) organizing members who actively practice preventive medicine, (2) participating in the process



of education of the members of this association in various medical developments and techniques within the discipline; and (3) speaking out in areas of law and politics which effect the practice of preventive medicine.

Preventive medicine is a practice or concept of medicine designed to lead to the prevention of diseases and physical infirmities, rather than dealing with them solely after they have manifested themselves in some physical fashion. It has principally emerged within the last ten years as a distinct branch of medicine. Orthodox medicine, as represented by the American Medical Association and the American Cancer Society rejects one of the basic premises of preventive medicine. Preventive medicine relies upon clinical results to show the success of preventive medicine techniques. Clinical results are rejected as being "testimonials" or "ancedotal." This is easily ascertained by the agency's review of the testimony presented by proponents of Laetrile during the hearings conducted by the agency.

Preventive medicine thus differs from

"orthodox" medicine. Orthodox medicine is crisis and disease oriented. It is based upon the treatment of diseases and physical infirmities once they have clearly manifested themselves. Preventive medicine is designed to lead to the maintenance of health and the prevention of forseeable infirmities. Thus rather than isolate and treat a specific cause of disease, preventive medicine takes the approach of supporting the body to maintain its own natural health rather than attacking disease with chemicals.

The Academy appears in this case to oppose the further entrenchment of the right of the Federal Food and Drug Administration (FDA) to limit the individual physician in his practice of medicine. This is accomplished by the FDA's limiting those medicinal substances which the physician may have available to utilize in his practice.

The Academy as an organization has not taken any stand with regard to the dispensation of Laetrile to the terminal ill cancer patient. Individual Academy members do, however, dispense Laetrile in the



course of their practice.

Proponents believe Laetrile is a body-supportive substance. It appears in its restorative propensities to assist the body to deal with cancer, rather than chemically attacking cancerous cells. This is within the Academy's conception of the proper practice of medicine.

Dispensing Laetrile is not a violation of law in states such as Washington. Eighteen states have now, by State law, authorized dispensing of Laetrile by qualified physicians. Two other states have had at least one-half of their legislatures pass bills which would allow such practice. It is apparent that there is a growing state trend to allow the dispensation of this medicinal substance within the sound discretion of the medical practitioner. The Federal Food and Drug Administration, through actions such as those reviewed by the lower court in this case, have endeavored to place severe limitations upon that practice.

The Academy has appeared as Amicus Curiae in the case of People v. Privitera, Jr. ____ Cal 3d ____ (Sup. Ct. No. CR-32978

1979), recently decided by the California Supreme Court. The Academy was interested in Privitera because that case focused on issues concerning the State's right to intrude upon or regulate the relationship between a physician and patient.

An essential ingredient in any medical practice is the free exercise of the physician's treatment according to his own conscience based upon the medical needs and choice of the patient. Governmental interference should be minimized.

## ADOPTION OF REFERENCE POINTS FROM THE BRIEF OF THE UNITED STATES

In this brief, the Academy would adopt by reference the sections of the Government's Brief entitled "Opinions Below", "Jurisdiction", "Questions Presented" and "Statutes Involved". The Academy would supplement the "Statement" section offered by the Government.

The case at bar first arose through the issuance of an injunction pursuant to the decision of the District Court of the Western District of Oklahoma, Luther L. Bohannon, Judge, 399 F. Supp 1208.



Judge Bohannon enjoined the Department of Health Education and Welfare (HEW) and the Food and Drug Administration from interference with a cancer patients' use of Laetrile. This injunction was issued pursuant to several findings which at this time are not pertinent to the case. On review, the Tenth Circuit Court of Appeals, at 542 F.2d 1137 (1976), affirmed the issuance of the injunction and remanded the case to the District Court to direct the Food and Drug Administration to prepare a full administrative record regarding the status of Laetrile in order that the entire matter could be reviewed by the Court.

The District Court, upon reviewing the findings of the Commission disagreed with the agency's analysis of the administrative record and found that the Commissioner's Ruling was arbitrary and capricious. Judge Bohannon again issued a sweeping injunction prohibiting the government from interference with the distribution and transportation of Laetrile.

The case was again reviewed by the Tenth Circuit Court of Appeals. It should be noted that this review was undertaken by three Judges other than those who heard

the original case. This time the Court of Appeals, in a very brief opinion, limited the trial court's second injunction and ordered the agency to

> permit procurement of Laetrile for intravenous injections administered by a licensed medical practitioner to persons who are certified by a licensed medical practitioner to be terminally ill in some form.

## I.
## THE PHYSICIAN-PATIENT RELATIONSHIP SHOULD BE UNDISTURBED UNLESS GOVERNMENTAL INTERFERENCE IS REASONABLE AND NECESSARY

There is a Constitutional right of a physician to contribute his professional judgment to the physician/patient relationship free from unnecessary and unreasonable intrusion by the Government. There also is the Constitutional right of a patient to exercise his private medical perogatives free from this interference.

Some balance must be maintained between the rights that vest with the citizens and those interests of the Government which are just and reasonable. The tenor of the Tenth Circuit Court of Appeals opinion and of the District Court's review of the



administrative record was to the effect that these balancing determinations should be made whenever possible based upon a full administrative record which can be reviewed by the Courts. The primary cases in the area of the physicains' and patients' rights are those noted briefly in the Government's Brief Roe v. Wade, 410 U.S. 113 (1973), and Doe v. Bolton, 410 U.S. 179 (1973). Particularly this is true of Doe v. Bolton.

In Doe v, Bolton, a Georgia Statute was under consideration which called for the initial decision of patient and physician regarding an abortion to be reviewed by Hospital Committees of other physicians. The mechanism being reviewed (which was stricken by the Court as violating Constitutional guidelines) concerned, therefore, the review of the treating physician's clinical judgment. In the circumstance at hand, the FDA has not compiled a record upon which it should seek to substitute the Commissioner's balancing of competing medical judgments for the individual physician's medical judgment.

In fact, the agency applies a different

standard to new drug applications not processed by pharmaceutical companies.

The Courts below seemed significantly aware of this. Considering a cancer victim's often rapid retrogression from apparent health to a terminal point, it cannot be doubted that any complex review mechanism that unnecessarily puts a grave strain on operational clinical judgment of an individual physician must be undertaken only if absolutely necessary. The Court noted in Doe v. Bolton, supra (at 197) with regard to the clinical judgment of a physician:

> "Saying all this however does not settle the issue of the Constitutional propriety of the Committee requirement. Viewing the Georgia statute as a whole, we see no constitutionally justifiable pertinence in the structure for the advance approval by the abortion committee. With regard to the protection of potential life, the medical judgment is already completed prior to the committee stage, and review by a committee once removed from the diagnosis is basically redundant. We are not cited to any other surgical procedure made subject to committee approval as a matter of state criminal law. The woman's right to receive medical care in



> accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview . . . We conclude that the interposition of the hospital abortion committee is unduly restrictive of the patient's rights and needs that, at this point, are substantiated by her personal physician. To ask more serves neither the hospital nor the State." (410 U.S. 197-198)

The Georgia Statute required independent examination of the patient by two other licensed physicians. Concerning the relationship of the physican and patient in our society, the Court noted as follows:

> The Statute's emphasis, as has been repetitively noted, is on the attending physician's 'best clinical judgment that an abortion is necessary.'
>
> That should be sufficient. The reasons for the presence of the conformation step in the statute are perhaps apparent, but they are insufficient to withstand constitutional challenge. Again, no other voluntary medical or surgical procedure for which Georgia requires confirmation by two other physicians has been cited to us. If a physician is licensed by the State, he

> is recognized by the State as capable of exercising acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are available remedies. Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on a physicians' right to practice. The attending physician will know when a consultation is advisable--the doubtful situation, the need for assurance when the medical decision is a delicate one, and the like. Physicians have followed this routine historically and know its usefulness and benefit for all concerned. It is still true today that '(r)eliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect that he (the physician) possess the requisite qualifications,' (Dent v. West Virginia, 129 U.S. 114, 122-23 (1889)). See United States v. Vuitch, 402 U.S., at 71 (Doe v. Bolton, 410 U.S., 199,200)

Finally, Justice Douglas in his concurring opinion was more cogent in his direct observation of these circumstances (at 219):

> Physicians, who speak to us in Doe through an amicus brief, complain of the Georgia Act's interference with their practice of their profession.



> The right of privacy has no more conspicuous place than in the physician-patient relationship, unless it be in the priest-penitent relationship.
>
> It is one thing for a patient to agree that his physician may consult with another physician about her case. It is quite a different matter for the State compulsorily to impose on that physician-patient relationship another layer of physicians. The right of privacy--the right to care for one's health and person and to seek out a physician of one's own choice protected by the Fourteenth Amendment--becomes a matter of theory, not a reality, when a multiple-physician-approval system is mandated by the State. The State licenses a physician. If he is derelict or faithless, the procedures available to punish him or to deprive him of his license are well known. He is entitled to procedural due process before professional disciplinary sanctions may be imposed. See In re Ruffalo, 390 U.S. 544. Crucial here, however is state-imposed control over the medical decision whether pregnancy should be interrupted. The good-faith decision of the patient's chosen physician is overridden and the final decision passed onto others in whose selection the patient has no part. This is a total destruction of the

> right of privacy between physician and patient and the intimacy of relation which that entails.

It should further be noted that Whalen v. Roe, 97 S.Ct. 869 (1977) did nothing to eliminate the physician's right nor denigrate that right other than to note that it was no stronger than that of the patient to whom it attaches. The Court, while not having directly addressed the entire issue, has begun to touch the area of the right of the physician to exercise his best medical judgment and the right of the patient to rely thereon. In examining the administrative record, it is urged by this Amicus Appearance that the Court bear in mind that a significant number of medical minds indicated their satisfaction with the relative safety and effectiveness of Laetrile, and the Court if at all possible should recognize the Constitutional rights of the physician and patient in order to leave this determination undisturbed. This Court should not allow the agency to substitute its judgment for the physician's judgment when evidence has been presented by Laetrile proponents of equal or greater value to the evidence in opposition to



Laetrile.

A medical doctor is, under general rule of evidence, deemed to be an expert in medical areas. This results from his educational background, experience and licensing. There is a direct reason for this. As long ago as Dent v. West Virginia, 129 U.S. 1114, 95 S.Ct. 231 (1889), the Court established the following proposition (at 1122,23):

> Few professsions require more careful preparation by one who seeks to enter it than that of medicine. It has to deal with all those subtle and mysterious influences upon which life and health depend and requires not only a knowledge of the properties of vegetable and mineral substances, but of the human body in all its complicated parts and their relation to each other, as well as their influence upon the mind. . . Everyone may have occasion to counsult (a physician), but comparatively few can judge the qualifications of learning and skill which he possesses. Reliance must be placed upon assurance given by his license. . . that he possesses the requisite qualifications.

Further,various Courts have cited with approval U.S. v. Freund, 290 F.411 (D.C. Mont. 1922). This case considered the

constitutionality of a prohibition era statute which restricted the amount of alcohol a physician could prescribe. The Court noted:

> It is an extravagant and unreasonable attempt to subordinate the judgment of the attending physician to that of Congress, with respect to matters with which the former alone is competent to deal and infringes upon the duty of a physician to prescribe in accordance with his honest judgment and upon the right of the patient to receive the benefit of the judgment of the physician of his choice. (emphasis added)

Without even discussing the doctrine of privacy, as originally formulated in the Olmstead dissenting opinion by Justice Brandeis, it can be seen that, in general, the medical judgment of a physician with proper training and proper scientific evidence and background has in many instances remained undisturbed by the Court. It is urged in this Amicus Appearance that the Court consider the fact that the delicate balance between the physician and patient is irreparably disturbed by allowing the agency to simply balance one group of



medical witnesses against another.

The Supreme Court of the State of California has recently addressed the issue of regulating Laetrile. People v. Privitera, et al., ____ Cal 3d ____ (1979) overruling People of the State of California v. Privitera, et al, 141 Cal. Rpt. 764 (1977). That as yet unreported decision of that Court was a five to two decision, with the two dissenters adopting the lower court decision.

The California Supreme Court majority simply held that the California Statute represented a reasonable intrusion by the State on the rights of both patients and physicians. That decision, however, dealt directly with the constitutionality of the California statute. The California Supreme Court differentiated that application of state power from Judge Bohannon's Rutherford decision. The Court noted that this Rutherford decision dealt with a class action by terminally ill cancer patients; the case before them dealt with criminal violation which was conspiracy to violate the laws of the State of California through the dispensation of an unrecognized cancer remedy. There is a specific California

Statute regulating the development of cancer treatments.

This does not, however, completely obviate the vitality of certain of the lower court rulings which recognized the constitutional arguments dealt with in this brief and accepted by Judge Bohannon.

This Court is urged to accept the reasoning of the Privitera court of appeals. The discussion at 141 Cal Rptr. 764, 770, will be briefly recreated here verbatim as it is exceptionally pertinent to these issues. The Court for other issues relied heavily upon the language of Rutherford v. United States, 438 F.Supp 1287(1978)(the California Supreme Court did not challenge the validity of this case doctrine established by Rutherford but differentiated it):

> Dr. Privitera asserts a separate and distinct constitutionally protected right--a zone of privacy--to prescribe, to treat patients whether in the orthodox mode--free from unjustified state interference.
>
> Whalen v. Roe, supra, ___U.S. ___(97 S.Ct. 869) accepts as a premise the existence of the right of the individual patient to choose independently with the advice of his physician to use or not to use



> a particular medication. Said the Supreme Court at page 878:
>
> "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication."

However, with respect to the doctor's right to freedom to treat, to minister to the sick, in Whalen v. Roe, supra, ___ U.S. ___ (97 S.Ct. 869), we have heretofore noted the Supreme Court's determination the "doctor's claim is derivative from, and therefore no stronger than, the patients'." Doe v. Bolton, supra, 410 U.S. 179 (97 S.Ct. 739), however, speaks spcifically of the doctor's right to administer medical care. Bolton involved a constitutionally defective statute requiring consent of two state licensed physicians other than the patient's own doctor before an abortion could be performed as well as advance approval of three members of the hospital staff where the abortion was to be performed. Concerning this statute the Supreme Court said:

> "The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview." Doe v. Bolton, supra, 410 U.S.

179, 197 (93 S.Ct. 739,750); emphasis added.)

Dr. Privitera additionally asserts an independent right to treat, not derived from or measured by his patient's right of choice, without first obtaining approval of the procedure or drug prescribed from a governmental board. He argues Health and Safety Code section 1707.1 invades this right. Again, as in the right of the patient, the doctor's asserted right must be first examined to determine its nature and thereby select the test, the degree of scrutiny to which the state interference will be put. The right found must be balanced against the state--the public interest protected.

Dr. Privitera's right, in relation to the patient, has been viewed traditionally as a species of economic interest rather than as "fundamental" akin to the privacy right. If a rational basis was found to support an encroachment, the statute was sustained.

While a dispassionate reading of the physician's licensing requirements raises some question concerning the total rationality of the licensing scheme, such standards are generally upheld as reasonable and necessary means of protecting the public health.

The more recent cases hint at the more profound right in the doctor. It is postulated: There exists in the doctor licensed to practice medicine a right, constitutional in nature, as



yet ill-defined, to treat and to treat by unorthodox modalities --as yet unapproved by the state board--an informed consenting patient.

Doe v. Bolton, supra, 410 U.S. 179, 201 (93 S.Ct. 739, 751), states if a physician is licensed by the state he is recognized by the state as capable of expressing acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are remedies available and "reliance must be placed on the assurance given by his license. . . that he possesses the requisite qualifications."

Roe v. Wade, supra, 410 U.S. 113, 163 (93 S.Ct. 705, 732), states concerning the termination of pregnancy during the first trimester:

> ". . .the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that, in his medical judgment, the patient's pregnancy should be terminated." (Emphasis added)

Reason, based on history, experience, supports the doctor's premise. To require prior state approval before advising--prescribing-administering--a new treatment modality for an informed consenting patient is to suppress innovation by the person best qualified to make medical progress. The treating doctor, the clinician, is at the cutting edge of medical knowledge. To require the doctor to use only orthodox

> "state sanctioned" methods of treatment under threat of criminal penalty for variance is to invite a repetition in California of the Soviet experience with "Lysenkoism." The mention of a requirement that licensed doctors must prescribe treat within "state sanctioned alternatives" raises the spector of medical stagnation at best, statism, paternalistic Big Brother at worst. It is by the alternatives to orthodoxy that medical progress has been made. A free, progressive society has an enormous stake in recognizing and protecting this right of the physician.

## II.

## THE CASE AT BAR CAN BE DISTINGUISHED FROM OTHER DETERMINATION OF FDA AUTHORITY AND OTHER LAETRILE CASES

The Government's Brief dealt with the case law standards set since the enactment of the 1962 Amendments to the Food and Drug Act requiring new drug applications (21 U.S. C. Section 355). These standards are delineated in U.S. v. Article of Drug "Bentex Ulcerine", 469 F.2d 875 (1972) and U.S. v. Articles of Drug "Colchicine", 442 F.Supp 1236 (19 ).

Prior to the case at bar the finding that a drug is a "new drug" as defined by 21 U.S.C. Section 321 (p) required an applica-



tion initially established by that agency. Once this was established, any exemptions sought under the "grandfather clause" were required to be established in each of the necessary element by the proponent. (The five elements cited in the Government's Brief are those established by previous case law.)

The Courts in the two above-cited cases held that a desirable record for such exemption should show a wide-spread usage of the drug in question, pursuant to adequate testing by recognized experts in a given medical area sufficient to establish the efficacy of that substance. This administrative showing should include the fact that the usages, labeling, and recommended dosages were the same as those factors prior to the triggering date of the 1962 Act as after that date. The Courts have further held that any change in one of these factors, or any additional claim for efficacy attributed to the drug after the triggering date, would require a new drug application with regard to these developments. It has been argued by the Government in previous cases that any

of these changes, even as slight as a labeling change, should require, as a matter of law a complete new drug application for the entire product as if it were not a pre-1962 drug.

Both of the cases cited above involved products which were distributed throughout a limited geographical area. Bentex Ulcerine was a localized medicinal product recommended for treatment of peptic ulcers. Colchicine was similarly limited to a geographical area as a treatment for Gran Mal seizures. There had been a slight labeling change over a period of years, and due to the small geographical area over which the products were distributed, the recognition by medical doctors for safety in use was limited to a relatively small geographical area.

Both Courts found it appropriate to prohibit transportation of that substance in interstate commerce as the FDA had sought. The FDA would have this authority until appropriate new drug applications had been completely processed and favorably passed upon by the agency. These Court holdings were based on a finding



that the safety of the substance was not sufficiently established within the terms of the grandfather clause.

Durovic v. Richardson, 479 F.2d 242 (7th Cir) (1973) dealt with the proposed cancer remedy Krebiozen. The Court here made a basic finding that even prior to the triggering date of October 10, 1962, in the case of a drug to be used as a treatment for a life-threatening disease, the term "safety" had incorporated the concept of effectiveness. The Court found that the proponents of Krebiozen had failed to establish by a preponderance of the evidence that the drug was both safe and effective within this construction of the Act.

This is the argument which is urged to this Court by the Government's Brief. This construction of statutory language was rejected by the Tenth Circuit Court of Appeal in its review of the case at bar. In its first decision in this case, the Court found implicitly that the addition of "effectiveness" requirement was a new one with the Acts' 1962 amendments. As the Court noted:

> Prior to the 1962 Amendment, the only prerequisite for a drug to avoid classification as a new drug was recognition that it was safe. But the 1962 Amendment added the requirement of "effectiveness" (citing statute). Rutherford v. United States, 542 F.2d 1137, 1141 (1976)

The Court placed the burden on remand with the agency for the creation of a record to show affirmatively and substantially by the evidence, that Laetrile was not only a new drug within the terms of the statutory enactment, but also that it was subject to a new drug application because it did not fall within any appropriate exemptions.

The Court noted in this regard at 1143:

> The FDA has argued that they have not issued any regulation or rule which specifically or positively forbids the administration of Laetrile. This is true. However, the FDA has made an administrative determination that Laetrile is a new drug and this places the Plaintiff in a position in which he has to admit that it is a new drug in order to get the FDA to move. As a result he could not be heard to say that they have effectively stymied the use of this drug. The FDA has done this without citing any facts whatsoever, merely a conclusion, and this is the kind of declaratory order that was before



> the Court in Weinberger v. Hynson, Wescott & Dunning, Inc., 412 U.S. 609, 625-27, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973)

In its analysis of the relationship between safety and efficacy requirements, and in its act of placing the burden upon the agency to establish, by a proper record, that the agency has authority over the distribution and transportation of Laetrile the Tenth Circuit has differed in its approach from the previous decisions. It is the balancing of these two approaches which this Court must undertake in rendering its opinion. Through this Amicus Appearance the Northwest Academy would urge the court to follow the approach of the Tenth Circuit Court of Appeals.

Laetrile has given rise to other judicial discussion of these issues. In these cases the Court has placed the burden upon the proponents of Laetrile to establish that the drug should be exempted from Federal Regulation. This line has been followed with the exception in Rizzo v. U.S., 432 F.Supp. 356 (1977) which followed the authority of the earlier Rutherford case.

In some of these cases this approach has

been appropriate. Cases have been brought by individual cancer patients seeking preliminary injunctions. Quite rightfully, these Courts have placed a high burden on the patient to establish at the preliminary injunction stage that there is a sound chance of the patient prevailing at trial. Unfortunately, in each of these cases where injunctions were denied, the patient was deceased long before the matter came to trial.

The first such case is Gadler v. U.S., 425 F.Supp. 244 (1977). Petitioner Gadler filed a Motion for Preliminary Injunction seeking to restrain government defendants from barring his personal importation of Laetrile from Mexico. The Court denied the requested injunction. The Court found that the substance was a "drug" within the meaning of the Act. The Court examined the various claims of the Petitioner for exemption, noting at the outset that a substantial burden was placed upon the Petitioner to establish a probability of success on the various issues when the matter went to trial. The Court took a posture similar to that urged here by the Government, finding that



the Petitioner had not carried his claim that the substance was not a new drug, nor that the provisions of the Act which allowed prohibition of the drug's movement in interstate commerce did not apply to his personal use of the substance. The Court denied the request for injunctive relief.

The case of Rizzo v. U.S. supra, arose after the first Rutherford decision from the Tenth Circuit Court of Appeals. Citing Rutherford as its principal authority, the Court granted injunctive relief to the Petitioner Rizzo, limiting the Government's intervention of his importation and usage of Laetrile. The Court felt that the Petitioner raised serious statutory and constitutional issues which were fairly designed for appropriate litigation. The Court further recognized that in balancing the equities between the needs of the agency and the needs of Rizzo, a cancer patient seeking access to a medication that he had determined was a desirable treatment, must have tipped this balance in his favor. The Court found that the patient would indeed suffer irreparable injury if the injunction was denied. He could readily anticipate

imminent death.

The Rizzo court addressed some specific statutory issues and found that these conflicting issues were indeed difficult and complex and ultimately in need of a careful determination. The Court addressed its own two-fold Constitutional concerns. Firstly, this Court was concerned with the individual's right to self determination in medical areas as a facet of his right to privacy.[1] Secondly, the Court was concerned with the lack of due process in the agency's actions regarding Rizzo.

The Rizzo Court noted that the parameters of an individual's right to privacy in medical elections had not been completely defined. Prior Supreme

1. It should be noted here, as related by author Robert L. Schwartz in the February 1979 issue of the American Bar Association Journal, that Doctor Benjamin Rush as one of the country's founding fathers felt that the only way to adequately protect this type of right to privacy was to create a right to medical thought similar to the right of religious freedom. Such right would have attached both to the patient and to the physician. Although this concept was not adopted directly by the founding fathers, it is of historical significance that this was a matter of concern at least to some of the founding fathers.



Court cases had dealt with some of these issues. See, Roe v. Wade, supra, and Doe v. Bolton, supra. The Court's concern was that such parameters as existed can not be infringed upon by Government action. The Court was further concerned that the agency's action brooked Rizzo's right to be free from deprivation of life, liberty and property without due process of law. The Court expressed grave concern that an individual such as Rizzo was simply not in a position to fund the type of new drug application the agency was requiring. This jeopardized his ability to protect his self-determination as well as his life, liberty and property.

The Rizzo Court also addressed one other issue of concern to the Northwest Academy. Rizzo was suffering from cancer of the pancreas. The Court analyzed in a brief discussion the recommended and recognized treatments considered safe and effective by the agency. Specifically, the Court considered the prescription of Fluororacil, a highly toxic drug which the Court noted was described by the manufacturer's own package insert:

> Fluororacil is a highly toxic drug with a narrow margin of safety. Therefore, patients should be carefully supervised since thereaputic response is unlikely to occur without some evidence of toxicity. Patients should be informed of expected toxic effects, particularly oral manisfestations. White blood counts with differential are recommended before each dose. Severe hemotological toxicity, gastrointestinal hemorrage and even death may result from the use of Fluoraracil despite meticulous selection of patients and careful adjustment of dosage.

These are the recent cases in which the Court's have considered the individual's right in these medical areas. Other cases as noted by the Government have considered Laetrile as a medical substance. All of these have been unfavorable to the drug's proponents. Most of these cases, however, involve small manufacturers or suppliers who were generating a substance and putting it into interstate commerce for sale. In this regard, the Federal District Courts have been particulary unreceptive to such parties.



## III.

## THE FDA HAS THE BURDEN OF ESTABLISHING THAT IT HAS AUTHORITY TO REGULATE THE DISTRIBUTION OF LAETRILE

The Tenth Circuit has for the first time required the Agency to meet the burden of establishing affirmatively its regulatory authority vis a vis Laetrile. Opinions of the District Court and the Tenth Circuit Court of Appeals contained a great deal of that which is an application of common sense and reasonable logic, rather than an application of existing law. Prior to these decisions, there had been little court action favorable to opponents of the wide-spread and wide-ranging authority exercised by the Food and Drug Administration.

Much of the case law in this area is not directly supportive of the actions taken by these courts below. These Courts have moved in a new direction with regard to the authority of the FDA. Since those decisions have been announced, other Courts have followed this lead, and curtailed the FDA's authority. It is perhaps the case that some trial courts were simply awaiting some legal authority for this

type of action.

Laetrile is a pharmaceutical product or medicinal substance that strikes against the grain of establishment medical research and development. It is not exceptionally costly nor complicated to produce. It is not a substance which is limited in its production to large pharmaceutical companies. The interests of the pharmaceutical companies is frequently the same as those of orthodox medicine. The development of this substance, for philosophical reasons, goes against the principals of modern orthodox medicine.

The FDA requirements for the processing of a new drug application require an extreme expenditure of time, energy and money. These expenditures can normally only be underwritten by pharmaceutical houses which have significant profit possibilities from the production of their pharmaceutical products. This has not been undertaken with regard to the substance Laetrile. Medicine's interests are frequently the same as those of the pharmaceutical industry.

As presently administered by the FDA



in cases of a new drug application, there is the necessary expenditure of resources beyond the capacity of anyone outside the established pharmaceutical industry. Without this expenditure, the applications are deemed incomplete by the FDA.

The Tenth Circuit Court of Appeals seemed aware of this financial discrepancy. Previous cases, including those cited by the Government place the burden on the proponents of the pharmaceutical product, even where the proponent was a single individual, to establish the right to exemption status for the product in question under the "Grandfather Clause" of the 1962 Act.

In several of these previous cases that pharmaceutical product was Laetrile. However, these cases lacked an administrative record. The first time the case at bar appeared before the Tenth Circuit Court of Appeals, this was acknowledged by the Court. The Court stated:

> From what has been said it is obvious that we are not in agreement with the trial court's opinion that the FDA has to approve or disapprove any new drug, even in the absence of

an application, that satisfies the statutory mandate. As we have noted, Section 505(b) of the Act specifically requires the filing of a new application by the proponent of a new drug. The FDA simply rules on the application as submitted.

(a) See H.R. Rep. No. 2139, 75th Cong. 3d Sess. (April 14, 1938) at 9:

> This provision (Section 505) will not put the Federal Government into the business of developing new drugs, nor will it require the Government to duplicate laboratory and clinical tests made by responsible manufacturers. The provision merely sets up a method for the authoritative review of the manufacturer's tests and will not unreasonably delay the introduction of new drugs in the market. It provides for court review of the decisinn of the administrative agency adverse to the manufacturer.

(See also H.R. Rep. No. 2464 87th Cong., 2d Sess. (September 22, 1973) at 3.)

Congress in writing Section 505 (b) was relying on the ability and willingness of the pharmaceutical companies to present new drugs. It follows that the FDA was not compelled to pursue



this new drug procedure in the absence of an application. (Citations omitted)

We are unable, however, to see how the FDA can avail the obligation of producing an administrative record to support its determination of the first and more fundamental issue that Laetrile is a new drug, for it is not a new drug merely because they say it is. Moreover, such a conclusory ruling precludes effective review under 5 U.S.C. Section 706 (2). Cf Weinberger v. Hynson, Wescott & Dunning Inc., supra which holds the new drug decision by way of 5 U.S.C. Section 554(e) to be reviewable in a district court. To support its determination the FDA in the case at bar would have to present substantial evidence to support that proposition that Laetrile is not generally recognized among qualified experts as "safe and effective": and that Laetrile is not grandfathered by either of the exemptions discussed above.

It seems doubtful that the FDA has in fact developed an administrative record adequate under 5 U.S.C. Section 554(c) and hence there is probably nothing which is presently available for a court to review. Nothing in the record

suggests that the FDA has dealt with Laetrile in a rule making proceeding under Section 701 of the Act, 21 U.S.C. Section 371, Compare National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688 (2d Cir. 1975). Hence, if this is true the appropriate procedure for the district court is to remand the case back to the FDA for proceedings adequate to develop a record supportive of the agency's determination the proceedings should give Laetrile proponents an opportunity to express their views. This is a result which is also supported by the Supreme Court decision in Weinberger v. Bentex Pharmaceuticals, 412 U.S. 645, 93 S.Ct. 2788, 37 L.Ed.2d 235 (1973). There the district court faced with a similar problem referred the matter to the FDA for initial determination. See 412 U.S. at 652-54, 93 S.Ct. 2788. The question whether the drug is to be recognized as "safe and effective" or was "grandfathered in" are "the kinds of issues particularly suited to initial determination by the FDA." Id. at 653, 93 S.Ct. at 2494. Rutherford v. United States, 542 F.2d 1137 (1976) at pp. 1143-1144.

Balancing these equities, and considering the Constitutional right of privacy



that accrues to the physician-patient relationship, it is reasonable to require the FDA to clearly establish the basis for its regulation of Laetrile.

## IV.

## THE FDA FAILED TO MEET ITS BURDEN OF SHOWING IT HAS THE AUTHORITY TO REGULATE LAETRILE

The Tenth Circuit Court of Appeals decision which is before this Court is that Court's second consideration of the Laetrile issue. This opinion is very brief by normal standards. The Court did not pass on the merits of Judge Bohannon's review of the FDA's administrative record. The Court held that it could not uphold the agency's action when the consideration was the "safety" and "effectiveness" of a substance which is proposed to be provided to "terminally ill" cancer patients after orthodox treatments have failed to restore these patients' health. We would also urge that the Court consider the merits of Judge Bohannon's review of the administrative record.

In line with the first decision of the

Tenth Circuit Court of Appeals, Judge Bohannon has correctly balanced the various equities of the parties. He has taken cognizance, as was done in Rizzo v. U.S. supra, (which cited as its basic authority the first Rutherford case, 542 F.2d 1137 (1976)), that the size of the pharmaceutical companies and the nature of "orthodox medicine" has meant that no standard has been applied to other orthodox cancer treatments similar to the one the agency has applied to Laetrile. The medicinal substances used in Chemotherapy cannot rationally be described as "effective" or "safe". The representation by medical authorities has been that these substances, though exceptionally hazardous to any individual's health, are necessary treatments; in a relatively small percentage of cases some remission of cancer cells can be achieved without completely leading to the termination of the patient.

Judge Bohannon noted that there is no "majority" medical opinion with regard to balancing such factors in cancer treatment. In point of fact, only the proponents experts had utilized Laetrile;



the opponents criticized their "standards". But the bureaucratic weight of the agency and its authority has been thrown behind the orthodox medical acceptance of Chemotherapy and not behind Laetrile. Both Judge Bohannon and the Tenth Circuit would require that the Government show that each Government intervention into the distribution and transportation of a medical product be necessary and reasonable, not simply concurred in by "orthodox" medicine.

Judge Bohannon also considered the Constitutional issues concerned in this conflict between the FDA and individual rights. These issues have already been discussed above.

## V.

## THE FDA HAS NO AUTHORITY TO INTERFERE WITH THE USE OF LAETRILE BY THE TERMINALLY ILL

The Tenth Circuit Court of Appeals in the decision on appeal to this Court, omits discussion of several aspects of the District Court's decision. The Court deals simply and briefly with the concept that the action, having been

brought by a class of terminally ill patients, must concern the issues of safety and efficacy of Laetrile as a drug when dispensed to such a class.

This brief has previously urged that each individual substance must be examined with regard to reasonable application of the agency's standards. The Court has held that, regardless of the drug in question, the terms "safety" and "effectiveness" have no medical application to the terminally ill as a class.

It is true, that the Court does not define the terms "terminally ill". The Tenth Circuit noted in its opinion that the determination of this medical status can be made by any licensed medical doctor who is competent to practice. Therefore, the determination as to whom the standards created by the Court shall apply should be left to licensed medical practitioner.

The Court relied upon no apparent case law or legal authority in formulating these standards. It noted that it was within its authority in directing the agency to compile an appropriate record.



It was within the authority of the District Court to review the findings and the District Court had done so. Further, the Court noted (citing Weinberger v. Hynson, Wescott & Dunning Inc., supra) that the Courts possess the power to review the determinations made by the agency, basing its considerations on determination of "all relevant questions of law".

The Court notes, at page 6(a) of the Petitioner's appendix, that with regard to terminally ill cancer patients, Laetrile is "as effective as anything else". The Court notes (again at 6(a)):

> We do not say that anything is safe for the persons concerned and nothing is effective, but it is apparent that no applicable or reasonable measure exits. (Emphasis provided)

The Government has argued that the real danger and lack of safety in a substance such as Laetrile is that unauthorized individuals may abuse the substance by obtaining it once it has been released into the market place. We would argue that this concept applies equally to all substances or products

regulated by the FDA. Any regulation is subject to abuse. If Laetrile is released some control will undoubtedly be placed over its usage within the guidelines established by the Court. The Court dealt with this issue in its opinion. The Court stated at pages 6(a) and 7(a) of the Government's appendix as follows:

> We are well aware of and have considered the argument that some patients will be victimized by unscrupulous persons who will seek to profit by offering Laetrile as a "cure". This is however not a legal matter, but an administrative or regulatory problem of the FDA.

The Court thus directly placed the burden on the FDA to carry out the Court's decision and also appropriate legislative mandates. It is no objection to such authority of the Court that the agency disagrees with the directive it has been given.

The Tenth Circuit did not deal directly with the issues dealt with by the District Court. It did not indicate that it disapproves of them; it simply did not discuss them. The Court noted specifically



that it did not reach the Constitutional issues discussed by the District Court.

The decision of the Tenth Circuit Court of Appeals had its own wisdom and its own logic, which this Amicus Appearance urges this Court to accept. The reasoning applied shows directly and logically the fallacy in the agency's thinking. We would urge the Court to consider that the reasonableness of each request and each situation must be determined by the agency by applying reasonableness and logic to each circumstance. The agency should not be permitted to simply fall back upon its own determination that no new drug application has been processed. We would further urge that the Court consider the issues addressed by the District Court, especially with regard to the Constitutional aspects of the case.

## CONCLUSION

The Northwest Academy of Preventive Medicine urges the Supreme Court to affirm the decision and holding of the Tenth Circuit Court of Appeals and the reasoning of the District Court.

Respectfully submitted,

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